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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,962	BRUGLIERA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 7, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-45* is/are pending in the application.

4a) Of the above claim(s) *41-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/142,108.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0903*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claim 40, drawn to a DNA construct, and SEQ ID NO:7, in the reply filed on June 7, 2006 is acknowledged.

The traversal is on the ground(s) that SEQ ID NO: 8 represents the amino acid sequence encoded by SEQ ID NO: 7 and should be thus be included in the examination.

Applicant's arguments are persuasive to the extent that they apply to nucleic acid sequences that encode the amino acid sequence of SEQ ID NO: 8. Accordingly, the nucleic acid sequence of SEQ ID NO:7 and nucleic acid sequences that encode the amino acid sequence of SEQ ID NO: 8 will be searched and examined in the instant application. The remaining nonelected sequences are withdrawn from consideration.

The traversal is also on the ground(s) that the restricted claims are not directed to inventions that are independent and distinct. In this regard Applicant notes that a key element of the DNA construct of group I resides in the specific nucleotide acid sequences contained in the DNA construct, and that the transgenic plant of Group II contains the same specific nucleotide acid sequences as the DNA construct of Group I. Applicant also notes that the DNA construct of Group I is made for producing the transgenic plant of GroupII, and that the altered color in the transgenic plant is the result of reducing the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase via one of the specified nucleotide acid sequences.

This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are either independent *or* distinct (MPEP § 803). This is also not found persuasive because Applicant's arguments are directed to

features not required of the plant claimed. The transgenic plant of claim 41 does not comprise the DNA construct of claim 40, nor is the identity of it's transgene specified; the transgenic plant of claim 41 is said only to comprise a nucleic acid molecule selected from the group consisting of: (1) a nucleotide sequence encoding an amino acid sequence consisting of SEQ ID NO: 8; and (2) a nucleotide sequence consisting of SEQ ID NO: 7. Further, claim 41 does not require that the tissue of the transgenic plant exhibit altered color as a consequence of reducing the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase via one of the specified nucleotide acid sequences; the transgenic plant of claim 41 is said only have tissue exhibiting altered color. The inventions are additionally separately classified, and require separate areas search with respect to the type of DNA construct in which the specific nucleotide acid sequences are contained (Group I), and with respect to plants that would comprise the specific nucleotide acid sequences, be transformable, and have tissue that exhibits altered color (Group II). Claims 41-45 are therefore withdrawn from consideration as being directed to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 40 is directed to a DNA construct capable of reducing expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant, said DNA construct comprising a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding an amino acid sequence consisting of: SEQ ID NO: 8; and (2) a nucleotide sequence consisting of SEQ ID NO: 7.

The specification describes SEQ ID NO:7 as a partial cDNA sequence obtained from *Arabidopsis* that encodes an amino acid sequence of SEQ ID NO: 8 that is homologous to a flavonoid 3'-hydroxylase (page 10; page 29; pages 67-71; pages 98-101). The specification does not describe the structural features of any DNA construct that functions to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant and that comprises a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding

an amino acid sequence consisting of: SEQ ID NO: 8; and (2) a nucleotide sequence consisting of SEQ ID NO: 7.

The Federal Circuit has recently clarified the application of the written description requirement to nucleic acid sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also affirmed the PTO's applicable standard for determining compliance with the written description requirement, quoting from the PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106, where it is set forth that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1613 (CAFC 2002).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses DNA constructs that function to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant and that comprise a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding an amino acid sequence consisting of: SEQ ID NO: 8; and (2) a nucleotide

sequence consisting of SEQ ID NO: 7, nor the structural features unique to the genus that are correlated with reducing the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 40 is directed to a DNA construct capable of reducing expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant, said DNA construct comprising a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding an amino acid sequence consisting of: SEQ ID NO: 8; and (2) a nucleotide sequence consisting of SEQ ID NO: 7.

The specification discloses the isolation from *Arabidopsis* of a partial cDNA sequence of SEQ ID NO:7 that encodes an amino acid sequence of SEQ ID NO: 8 that is homologous to a flavonoid 3'-hydroxylase (pages 67-71). The specification does not disclose how to make a DNA construct comprising a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding an amino acid sequence consisting of: SEQ ID NO: 8; and (2) a nucleotide sequence consisting of SEQ ID NO: 7 that can be used to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant, or which plants would comprise an endogenous gene with sufficient homology to the construct sequences to be subject to a reduction in expression.

The claimed invention is not enabled because the ability of a DNA construct to reduce the expression of an endogenous gene in a plant is unpredictable, as the ability of an antisense transcript to suppress gene expression depends on multiple variables which include but are not limited to the length of the antisense transcript, its position relative to the parent gene, and the degree of homology between the antisense transcript and the gene to be suppressed.

See, for example, Sandler S.J. et al. (Inhibition of gene expression in transformed plants by antisense RNA. Plant Molecular Biology, 1988, Vol. 11, No. 3, pages 301-310), who teach that DNA fragments encoding different portions of the nopaline synthase gene, when expressed as antisense transcripts, vary in their ability to inhibit nopaline synthase gene expression (page 308 column 2 and Table 4, page 309 column 1 first full paragraph). Antisense transcripts downstream from the Cla I site (nucleotide 373) effectively suppressed nopaline synthase gene expression, whereas the full length antisense transcript and the antisense transcript upstream from the Cla I site (nucleotides 1 to 373) did not (id).

See also, for example, van der Krol A.R. et al. (Inhibition of flower pigmentation by antisense CHS genes: promoter and minimal sequence requirements for the antisense effect. Plant Mol Biol. 1990 Apr;14(4):457-66), who teach a method of decreasing the expression of an endogenous petunia chalcone synthase gene by transforming petunia cells with chimeric genes comprising chalcone synthase (CHS) coding sequences operably linked in an antisense orientation to a CaMV 35S constitutive promoter. The full length CHS cDNA and CHS sequences encoding half-length or quarter-length RNA complementary to the 3' half of the CHS mRNA decreased the expression of endogenous CHS, whereas half-length RNA complementary to the 5' half of the CHS mRNA did not (page 460 Figures 1 and 2;page 461 Figure 3).

See additionally, for example, Waterhouse et al. (Virus resistance and gene silencing: killing the messenger. Trends Plant Sci. 1999 Nov;4(11):452-457), who teach that antisense suppression of gene expression requires a high degree of sequence homology (>75%) between the endogenous sequence and the antisense transgene to be effective (page 453 column 1 second full paragraph).

In the instant case the specification does not provide sufficient guidance with respect to how to make a DNA construct comprising a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding an amino acid sequence consisting of: SEQ ID NO: 8; and (2) a nucleotide sequence consisting of SEQ ID NO: 7 that can be used to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant, or with respect to which plants would comprise an endogenous gene with sufficient homology to the construct sequences to be subject to a reduction in expression. Absent such guidance one skilled in the art would have to make a variety of different DNA constructs comprising the recited sequences and test each one in a variety of different plant species in order to determine which DNA constructs, if any, can reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a plant. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

8/18/06